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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/349,489	12/02/1994	DAVID B. RING	0999.001	6479

7590 07/11/2005

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Mailed

Office Action Summary	Application No.	Applicant(s)	
	08/349,489	RING, DAVID B.	
	Examiner	Art Unit	
	Anne Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of new grounds of rejection, the finality of the previous Office action is **withdrawn** and prosecution on the merits continues. The after-final amendment filed 3/11/2005 is acknowledged. Claim 15 was canceled.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, and 8 are pending and examined on the merits.

Claim Rejections Withdrawn:

4. The rejection of claims 1-3 and 8 under 35 U.S.C. 102(b) as being anticipated by Weiner (Weiner, L.M. et al. Cancer Res. 53: 94-100, 1993, Jan. 1; previously cited) is withdrawn in view of the amendment.

The rejection of claims 1-3 and 8 as being anticipated by Weiner is withdrawn because Weiner teach the methods of administering the 2B1 bispecific antibody to scid mice, whereas the claims are drawn to methods comprising administering the 2B1 antibody to a human patient. Therefore, Weiner fails to teach the limitation of administering the 2B1 bispecific antibody to humans in an amount sufficient to induce an antibody response to the second antigen (2B1 binds to FcγRIII and to c-erbB-2; c-erbB-2, in this case is "the second antigen"). Furthermore, Weiner fails to provide a motivation to perform the method in a human, because Weiner fails to teach

that performing the method in a scid mouse resulted in the production of an antibody response to the 2B1 bispecific antibody. Therefore, Weiner provides no motivation to determine the appropriate dose levels in a human for the purpose of producing an immune response to the second antigen in a human.

5. The rejection of claim 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the cancellation of claim 15.

6. The rejection of claims 1-3 and 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

7. The rejection of claims 1-3 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

New Grounds of Rejection:

8. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Ring (U.S. Patent 5,959,084; issued Sep. 29, 1999; effective filing date Oct. 29, 1990) as evidenced by Clark (Clark, J.I. et al., Cancer Immunol. Immunother. 44(5): 265-272, 1997) and by Weiner (Weiner, L.M. et al, Cancer Research, 55: 4586-4593, 1995).

Applicant's arguments have been carefully considered, but fail to persuade. Applicants argue that the examiner has not provided any evidence that dosages used in ring would be the

same as those used in the claimed methods, and that therefore, the method of Ring is not inherently the same as the claimed methods. As discussed in previous Office actions, Ring teaches bispecific antibodies that bind to FcγRIII and to p-glycoprotein, and methods of administering bispecific antibodies to patients (col. 24, line 63 – col. 25, line 24). Because the instant specification fails to teach that the amounts of bispecific antibodies that would be sufficient to produce antibodies in a patient are different from the amounts that would be sufficient to kill cancer cells when injected in a patient, it is assumed that because the steps of the claimed methods are the same as those of Ring's methods (administration of a bispecific antibody within the scope of bispecific antibodies recited in the claims), that the methods of Ring inherently result in the production of antibodies. Thus, Ring teaches methods that are the same as that claimed because Ring teaches a method comprising the same active steps of the claimed methods (i.e. same antibody, same step of administering to a patient).

In further support of this argument, the evidence of Clarke (1997) and Weiner (1995) are provided. Weiner teaches a method of using a bispecific antibody for the purpose of treating cancer where the intended effect is to produce a cellular response against the tumor. The dosages used in Weiner are 1.0 mg/m^2, 2.5 mg/m^2 and 5.0 mg/m^2 (see abstract). These are dosages used in human patients. Clarke teaches a method of using a bispecific antibody for the purpose of treating cancer, where the production of an antibody response is observed, and the antibody response produces antibodies to the second antigen (in this case anti-c-erbB2 antigen, see page 266, 1st column, 2nd full paragraph). The dosages used in Clarke are 1.0 mg/m^2, 2.5 mg/m^2 and 5.0 mg/m^2 (see "Materials and Methods", page 266). In both Weiner and Clarke the same bispecific antibody, 2B1, is used. Therefore, evidence is provided that the claimed

methods are inherently the same as the methods taught by Ring, because it appears that the amount of a bispecific antibody used with the intention of producing a cellular response is the same as the amount of a bispecific antibody used with the intention of producing an antibody response.

Conclusion

No claim is allowed. Claim 8 is objected to for depending from a rejected claim, and would be allowable if rewritten as an independent claim.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
July 11, 2005